

REMARKS

Claims 1-38 were pending the application. Claims 1-7, 35, 36, 37, and 38 have been amended. Accordingly, upon entry of this amendment, claims 1-38 will remain pending.

Support for the amendments to claims 1-7, 35, 36, 37, and 38 may be found throughout the specification, including the originally filed claims.

No new matter has been added. Any amendments to the claims was done solely to more particularly point out and distinctly claim the subject matter of Applicants' invention in order to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Application Status

Applicants acknowledge the Examiner's indication that "[t]he Notice to Comply mailed on July 16, 2001 (Paper No. 5) was in error" and that "[t]he amendment filed by Applicants on June 20, 2001 amended the sequence listing to effectively comply with the sequence rules." Applicants thank the Examiner for her assistance in correcting this error.

Election/Restriction

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- | | |
|---------------|--|
| SuperGroup A: | Claims 1-17 and 36-38, drawn to nucleic acid molecules, vectors, host cells, and methods of making a polypeptide, classified in class 435, subclass 183. |
| SuperGroup B: | Claims 18-24, drawn to polypeptides, classified in class 435, subclass 183. |
| SuperGroup C: | Claims 25-34, drawn to methods of making fine chemicals, classified in class 435, subclass 41. |

SuperGroup D: Claim 35, drawn to methods for diagnosing the presence or activity of DNA sequences of *C. diphtheriae*, classified in class 435, subclass 6.

SuperGroup E: Claim 35, drawn to methods for diagnosing the presence or activity of protein sequences of *C. diphtheriae*, classified in class 435, subclass 7.1.

Applicants hereby elect, *without traverse*, SuperGroup A (claims 1-17 and 36-38) under 35 U.S.C. §121 for prosecution in the present application.

At pages 2-3 of the instant Restriction Requirement, the Examiner states that:

Each SuperGroup above is further divided into Groups related to each particular sequence (enzyme) claimed from Table 1...[f]or election purposes, Applicants must identify a Group (not just a SuperGroup) to be examined; this Group ***must be comprised*** of the following:

- (1) a SuperGroup, as noted above, **and**
- (2) a particular sequence (gene) from Table 1.

At pages 8-9, the Examiner further states that

It would be burdensome to examiner any more than one DNA sequence disclosed together with other DNA sequences....The M.P.E.P. states that “***up to ten independent and distinct sequences will be examined in a single application without restriction***” (see ***M.P.E.P. 803.04***) (emphasis added). However, *any* DNA which encodes the disclosed polypeptides are claimed; the search for a specific nucleic acid sequence is different from the search for all possible nucleic acid sequences encoding a particular protein, even if that protein is encoded by the original nucleic acid sequence. The examination of *any one* exact DNA sequence or any DNA encoding *any one* exact protein sequence must be searched to adequately search the claims, as written. This is a genus of DNA sequences that is many more than 10 individual sequences.

Applicants hereby elect SEQ ID NO:1, *with traverse*. Applicants further elect SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, and SEQ ID NO:21. Applicants respectfully submit that the policy set forth in 1192 O.G. 68 (Nov. 19, 1996), which the Examiner references, clearly provides that a ***reasonable number*** of sequences are allowed to be claimed in a single application. Ten sequences is a reasonable number of sequences to be examined in a single application. (M.P.E.P. §803.04). Applicants respectfully submit that the claims, as amended, are directed to isolated nucleic acid molecule comprising the nucleotide sequence of any one of ten nucleotide sequences (SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21). Accordingly, contrary to the Examiner's assertion that *any* DNA which encodes the disclosed polypeptides are claimed, the claims as amended are directed to ten nucleotide sequences.

Therefore, in the interest of saving considerable time and cost to Applicants and the United States Patent Office, and in accordance with 1192 O.G. 68 (Nov. 19, 1996), Applicants respectfully request that at least 10 sequences be examined in the instant application.

Furthermore, it is the Applicants' position that, with respect to the claimed nucleotide sequences, a species election for searching purposes would be more appropriate in this situation.

Applicants respectfully submit that a sufficient search and examination with respect to the claimed nucleotide sequences can be made without serious burden on the Examiner. As the M.P.E.P. states:

[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803.

Applicants respectfully submit that the searches with regard to each SEQ ID NO. would be co-extensive and would not involve a serious burden on the Examiner.

Applicants therefore request that the Examiner re-characterize the restriction requirement with respect to the SEQ ID NOs. as a species election requirement.

It is the Applicants' understanding that under 35 U.S.C. §121, an election of a single species for prosecution on the merits is required, to which the claims will be restricted if no generic claim is finally held allowable. Applicants submits that claim 1 is generic. Applicants further understand that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent from or otherwise include all the limitations of an allowed generic claims as provided by 37 C.F.R. §1.41 *et seq.*

Accordingly, within Group I, Applicants hereby further elect the species of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, and SEQ ID NO:21 for search purposes only. Applicants even further elect the species of SEQ ID NO:1 for search purposes only.

Applicants reserve the right to traverse the above restriction with respect to non-elected SuperGroups B-E in this or subsequent applications.

Notice of Possible Rejoinder

Applicants acknowledge that the Examiner has stated that

if product claims of SuperGroup A are found directed to an allowable product, then related methods claims (using the particular, patentable DNA product) in SuperGroups C and D, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P §821.04, *In re Ochiai*, and *In re Brouwer*).

The Examiner further states that "[s]ince process claims in SuperGroups C and D would be rejoined and fully examined for patentability under 37 C.F.R. §1.104, Applicants are

instructed to amend said claims as deemed necessary according to rejections made against the elected claims.”

SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,



Elizabeth A. Hanley, Esq.
Registration No. 33,505
Attorney for Applicants

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109
Tel. (617) 227-7400

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-7, 35, 36, 37, and 38 have been amended as follows:

1. **(Amended)** An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, or a complement thereof ~~from *Corynebacterium glutamicum* encoding an SMP protein, or a portion thereof, provided that the nucleic acid molecule does not consist of any of the F-designated genes set forth in Table 1.~~

2. **(Amended)** The isolated nucleic acid molecule of claim 1, wherein said nucleic acid molecule encodes an SMP ~~protein~~ polypeptide involved in the production of a fine chemical.

3. **(Amended)** An isolated *Corynebacterium glutamicum* nucleic acid molecule ~~selected from the group consisting of those sequences set forth in Appendix A, or a portion thereof, provided that the nucleic acid molecule does not consist of any of the F-designated genes set forth in Table 1~~ comprising the nucleotide sequence of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, or the complement thereof.

4. **(Amended)** An isolated nucleic acid molecule which encodes a polypeptide ~~sequence selected from the group consisting of those sequences set forth in Appendix B, provided that the nucleic acid molecule does not consist of any of the F-designated genes set forth in Table 1~~ comprising the amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, or SEQ ID NO:22.

5. **(Amended)** An isolated nucleic acid molecule which encodes a naturally occurring allelic variant of a *Corynebacterium glutamicum* polypeptide ~~selected from the group of amino acid sequences consisting of those sequences set forth in~~

~~Appendix B, provided that the nucleic acid molecule does not consist of any of the F-designated genes set forth in Table 1~~ comprising the amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, or SEQ ID NO:22, wherein the nucleic acid molecule hybridizes to the complement of a nucleic acid molecule consisting of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, in 6X SSC at 45°C, followed by one or more washes in 0.2X SSC, 0.1% SDS at 50-65°C.

6. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence which ~~is at least 50% homologous to~~ has at least 50% identity with the a nucleotide sequence ~~selected from the group consisting of those sequences set forth in Appendix A, or a portion thereof, provided that the nucleic acid molecule does not consist of any of the F-designated genes set forth in Table 1~~ of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, or the complement thereof.

7. (Amended) An isolated nucleic acid molecule comprising a fragment of at least 15 nucleotides of ~~a nucleic acid comprising a~~ the nucleotide sequence of ~~selected from the group consisting of those sequences set forth in Appendix A, provided that the nucleic acid molecule does not consist of any of the F-designated genes set forth in Table 1~~ SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, or the complement thereof.

35. (Amended) A method for diagnosing the presence or activity of *Corynebacterium diphtheriae* in a subject, comprising detecting the presence of one or more of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, or the complement thereof ~~the sequences set forth in Appendix A or Appendix B in the subject, provided that the sequences are not or are not encoded by any of the F-designated sequences set forth in Table 1~~, thereby diagnosing the presence or activity of *Corynebacterium diphtheriae* in the subject.

36. (Amended) A host cell comprising a the nucleic acid molecule of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, or the complement thereof selected from the group consisting of the nucleic acid molecules set forth in Appendix A, wherein the nucleic acid molecule is disrupted.

37. (Amended) A host cell comprising a the nucleic acid molecule of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, or SEQ ID NO:21, or the complement thereof selected from the group consisting of the nucleic acid molecules set forth in Appendix A, wherein the nucleic acid molecule comprises one or more nucleic acid modifications ~~from the sequence set forth in Appendix A~~.

38. (Amended) A host cell comprising a the nucleic acid molecule of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, SEQ ID NO:19, and SEQ ID NO:21, or the complement thereof selected from the group consisting of the nucleic acid molecules set forth in Appendix A, wherein the regulatory region of the nucleic acid molecule is modified relative to the wild-type regulatory region of the molecule.